

Mr. Chairman and committee members, my name is Vicki Rice, I am one of the five current members of the Montana Board of Clinical Laboratory Science Practitioners. I was appointed in 2012. I am also a CLS Practitioner licensee practicing in Montana for the last 32 years, 27 of those as the Lab Manager of the VA Montana Ft. Harrison Pathology and Laboratory Medicine Service. I am pleased to be here today to discuss how licensure of Clinical Laboratory professionals in our state of Montana, effective for the last 20 years, has been key in protecting the public health of all Montanans as well as better ensuring the high quality of healthcare delivered to each Montanan.

Our board oversees more than 900 licensees in the state. Within the standard, there are two levels of practice. The qualifications for those levels of practice are modeled after the qualification standards set by the American Society of Clinical Pathologists Board of Certification designed to certify Medical Laboratory Technicians having an associate degree and specialized training, and Medical Laboratory Technologists who are required to have a BA or BS and special training. Both certifications require passing a standardized exam.

Without the consumer-patient oriented, better, and stronger personnel standards mandated by Montana's licensure of these vital Laboratory Practitioners, the individuals employed to perform this important technical work would be regulated solely by the federal law known as the Clinical Laboratory Improvement Act (CLIA). Under CLIA's standards, high school graduates with minimal training can perform tests considered 'moderately complex' by the FDA with minimal proof of competency. In addition to specific educational, training and certification requirements of the clinical laboratory science practitioners,, Montana Licensure requires practitioners to complete ongoing continuing education in this rapidly changing field. Continuing education is not mandated by CLIA for any individual!! (Emphasize in your presentation). The Montana Legislature wisely saw the value of these higher standards 20 years ago when requiring licensure of laboratory personnel in our state. This licensure requirement insures that only those with the proper entry level education, specialized training and ongoing continuing education can perform laboratory tests in Montana.

The FDA determines the 'complexity' of all standardized tests on the market. The simplest type of test is considered 'WAIVED' by the FDA. These are testing methods that are supposed to be 'dummy proof'. An example of one of these would be similar to a pregnancy test device that one can purchase over the counter. The FDA gauges these methods as WAIVED and there are no personnel standards established that control who

can perform these tests. The next FDA category of testing methods is Moderately complex. As mentioned above, a 'competent' high school graduate can perform these tests, under CLIA standards. There are a huge number of tests in this category; the FDA complexity level is based primarily on the instrument or method used to perform the test, not the importance or criticality of the test in the healthcare setting. A high school graduate under CLIA standards can perform all the tests usually taken at your typical annual physical exam. The PSA test that many men follow as they age to indicate a risk of Prostate cancer is run on moderately complex platforms. Would you like to be the patient holding a result showing an elevated PSA, then recommended to undergo a painful prostate biopsy because the 'competent' HS graduate made a serious error due to a lack of educational background in the methods used to detect instrument malfunction? Probably not.

To clarify the summary information prepared for the committee, it is true that a LABORATORY must hold a CLIA certificate in order to bill Medicare/Medicaid. It is **NOT TRUE**, as the summary information suggests, that any of the **testing personnel** in that lab must be certified. CLIA provides certification for a **Laboratory only** and does not certify individual testing professionals. This is where Montana's law, requiring licensure of CLS Practitioners and the Board's oversight serve to protect the health of Montanans.

Montana's clinical laboratory professionals work in the public health sector, playing a major role in helping to limit the spread of disease by identifying specific communicable conditions – think of the recent pertussis outbreaks in Montana teenagers, for example. Analysis performed then by the public health laboratory professionals resulted both in limiting exposure by identifying infected individuals as well as raising the level of public understanding about the need to boost immunity by following recommended immunization schedules. Other Montana licensed clinical laboratory professionals work in the individual healthcare setting, performing testing on healthy and sick Montanans. I say this to underline that these unique professionals have a **dual role** in that they both protect the **public health** as well as serving as experts in the identification of disease that effects the healthcare of every **individual Montanan**.

A widely publicized statistic claims 70% of the information in a patient chart or electronic record is comprised of laboratory data. This fact underscores the **REQUIREMENT** that qualified, educated and trained professionals produce this data that literally contributes to life and death decisions every day across the state. How would you like to be the Montanan seeking healthcare for liver function abnormalities, finding, after undergoing

diagnostic tests, that no identifiable disease is responsible. Only much later you discover that your Hepatitis test was misread by a very minimally qualified employee and that you have an underlying contagious illness that could have been treated. At this stage, your liver is too damaged and transplant or imminent death are the only two possible outcomes. More commonly, a simple misreported potassium or glucose level could lead to potentially lethal treatment decisions.

State licensure of the CLS practitioners provides the best mechanism to assure that clinical laboratory services are performed with an adequate level of professional competence by requiring appropriate entry level qualifications for individuals engaged in the practice of clinical laboratory science in all settings. Many national professional organizations including the American Society for Clinical Laboratory Science, the College of American Pathologists and the American Society of Clinical Pathologists support Montana state licensure. There is a common assumption that medical laboratories are already REQUIRED to hire only certified staff. Under CLIA alone, this assumption is entirely wrong. CLIA personnel requirements, as I stated earlier, set the bar too low to assure competency. Clinical Laboratory Science Practitioner licensing in Montana raises that bar and protects the health of those receiving care in our state. If ever there was a compelling need for licensure, it is for those who perform the laboratory testing that directs the diagnosis and treatment of the multitude of diseases and conditions affecting our citizens.

We would urge the committee to maintain the status quo requiring licensure of CLS practitioners with the Board continuing to assure that levels of competency are met by all practitioners.

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